Introduction to Syringe Infusion

Syringe infusion is a system for delivering small-volume parenteral drugs intermittently. The majority of candidates for this intravenous (IV) delivery system include drug doses which can be diluted in 1 to 40 mL volumes and infused over periods of at least one minute to 120 minutes. Standard, inexpensive 3 to 60 mL disposable syringes act as the drug container for most of these doses.

Common examples of syringe infusion drugs include:

- cephalosporins
- penicillins
- anti-emetics
- H2 antagonists
- aminoglycosides
- steroids
- diuretics
- cardiac drugs
- other antibiotics

The Baxa MicroFuse™ Infuser accepts Becton-Dickinson (B-D), Monoject, and Terumo disposable syringes in sizes from 5 to 140 cc. The availability of 100 and 140 mL syringes allows delivery of a few more drugs requiring 100 mL dilutions using a syringe infuser. The Operator Manual provides complete Reference Charts for determining maximum fill volumes for different syringe sizes and manufacturers.

For any size syringe, the syringe infuser pushes the syringe barrel down at a predetermined rate to administer the drug solution. Syringe infusion is a simple, cost-effective alternative to minibags and IV push doses that meet the characteristics above.

Engineering Guide Overview

The Baxa MicroFuse Infuser offers a number of clinical and operational benefits for intermittent drug delivery. Basic information on syringe infusion and the use of the MicroFuse Infuser, along with reference charts for syringe filling and drug reconstitution are included in the *MicroFuse Pharmacy Reference Guide*. This Biomedical Engineering Reference Guide provides detailed information on the design process for the development of the infuser, testing and validation data and descriptions of its functional and engineering features.

This guide is divided into the following sections:

Syringe infusion is an efficient and cost-effective means of delivering small-volume intermittent IV therapies. Among the other alternatives: gravity infusion systems (ex.: minibags), elastomeric devices, ambulatory electronic pumps, and stationary pumps. The primary reasons cited for using syringe infusers over other delivery methods are lower material costs and improved patient care. The growth of syringe infusion for intermittent IV delivery, particularly in comparison with minibag systems, has been due to its accurate and consistent delivery, which reduces vein irritation, and improved pharmacokinetic monitoring.

The Baxa MicroFuse Infuser product line includes three standard product configurations:

- **MicroFuse Dual Rate Infuser –** for standard intermittent therapies infused over one to 120 minutes in dilution volumes of 1 to 100 mL. Two pre-set flow rates: NORMAL infuses most therapies over 20 – 40 minutes; SLOW infuses most doses over 60 to 120 minutes.
- **MicroFuse Rapid Rate Infuser** – designed for infusing adenosine over 4 to 6 minutes at rate 1. Rate 2 slows the infusion by about 30% (ex.: 140 mcg/kg/min to 100 mcg/kg/min). This infuser provides a safe and effective delivery mechanism for small-volume IV therapies requiring controlled push or bolus infusion.
- **MicroFuse Extended Rate Infuser** – designed for specialized continuous infusion applications. Its two rates accommodate standard infusions over 20 to 40 minutes (Rate 1) or extended infusions over 4 to 24 hours (Rate 2). Applications include continuous infusion of beta lactam antibiotics, 12-to-24 hour KVO or TKO infusion, and administration of Desferal® (deferoxamine mesylate).

Basic Operation

The MicroFuse Infuser operates on two standard alkaline C-cell batteries for a minimum life of 400 hours of operation. The least expensive of the electromechanical IV delivery devices, these infusers are volumetric pumps which use simple electronic or drive mechanisms for controlled delivery.

The MicroFuse Syringe Barrel Holder secures the filled syringe in place. Once the infuser is turned ON, the syringe driver arm depresses the syringe plunger at a fixed rate, administering the contents of the syringe through the administration set tubing and into the patient access site. A microprocessor control operates at a constant delivery rate, and can infuse the syringe contents against a back pressure of $\pm$ 100 mm Hg.

MicroFuse Infusers have a full complement of alarms which signal: end of infusion, occlusion detection, low battery, maintenance required, and internal malfunction. Alarms are indicated by flashing lights and an audible chime. Audible chimes may be placed in MUTE mode by pressing the Alarm Mute switch for two full seconds. NOTE: An internal malfunction alarm will override the mute feature.

Detailed product drawings and operating procedures are included in the MicroFuse Operator Manual.

MicroFuse Product Development

Baxa Corporation manufactures according to the Federal (FDA) requirements for design control. The purpose of design control is to ensure that appropriate product performance requirements are established, translated into design specifications, and that these requirements are met once the product is released to production.

Design Control

Baxa Corporation's design control system is a set of practices, processes, and procedure which ensure that our products meet total quality system requirements. These practices, processes and procedures are called *design controls*. The elements of our design control program are:

- Design and development planning
- Design inputs
- Design outputs
- Design review
- Design verification
- Design validation
- Design changes
- Design transfer
- Design History File

Design controls span the entire life cycle of the MicroFuse Infuser. Beginning with the product's initial release and continuing through either obsolescence or replacement, these controls terminate only when the product is no longer supported by the corporation.

Design and development of the MicroFuse Infuser began in August 1996 with a New Product Request to redesign the original Dual Rate Infuser marketed and sold by Baxa at that time. In this request, basic design requirements were identified under three major topics: **Constraints, Improvements to Durability, and Improvements in Performance**. The design requirements detailed resulted from an analysis of historical complaints, customer feedback and market research on competitive products. The entire development process for the MicroFuse Infuser was conducted by a multi-disciplinary team, with an engineer serving as project manager. Specific details on functional and engineering features of the MicroFuse Infuser are detailed in the next section.

Design Inputs

Design *inputs* for the MicroFuse Infuser were established early during the prototype development and planning phase of the program. Prior to the development of design inputs, a detailed risk analysis was performed, as well as a thorough analysis of customer complaints on the previous product. As engineering work continued on the product, these inputs evolved, supported by internal Baxa focus group discussions. Customer preference feedback was solicited on working prototypes which further defined design considerations. The final set of product design inputs responded to engineering decisions, marketing recommendations, customer complaint notes, and customer survey data encompassing development from prototype to post production.

Design Outputs

Design *outputs* for the MicroFuse Infuser were derived during the design process as a result of engineering action, including hazard/risk analysis, risk reduction and technical staff interaction. These design outputs directly correlate to the 24 identified design inputs for the MicroFuse Infuser.

Once the design outputs were established, they served as the baseline for verification testing of the MicroFuse Infuser. To ensure adherence to design input criteria, a master matrix was prepared which linked the results of the hazard identification, risk assessment and risk reduction to the comparison of the design inputs to outputs, then linked the outputs to specific verification testing by direct reference. This process acknowledges the possibility that testing may indicate engineering issues which must be addressed by the design team.

Ongoing design control activities ensure the integrity of product design following its release for manufacture. The Baxa Corrective and Preventive Action Program (CAPA) provides the mechanism for monitoring customer contacts and complaints and ensuring an appropriate response or product refinement.

Standards and Guidance Documents

The following standards and guidance documents were used to develop the input/output matrix for the MicroFuse Infusers:

CEI/IEC 60601-1	General requirements for safety for medical electrical equipment
CEI/IEC 60601-2-24	Particular requirements for safety of infusion pumps and controllers
prEN 1441	Risk analysis
prEN 6060-1-2	Electromagnetic compatibility
CEI/IEC 475	Electrically generated alarm signals
prEN 980	Graphical symbols for use in labeling medical devices
ANSI/AAMI HE48-1993	Human factors engineering guidelines and preferred practices for the design of medical devices
ANSI/AAMI ID26-1992	Infusion devices

Design Control Guidance for Medical Device Manufacturers, Food and Drug Administration, Center for Devices and Radiological Health

Do It By Design, An Introduction to Human Factors in Medical Devices, Food and Drug Administration, Center for Devices and Radiological Health

Product Testing

Baxa products undergo a series of verification and validation tests prior to their release for sale. Simply put, validation testing determines if we have made the "right" product. Does it meet the customer's needs? Verification testing determines if the product has been made right. Does it meet our specifications? Does it pass in-process testing? Taking the design inputs, then validating that the product functions as desired, results in the features and benefits described in our product literature.

Verification and Validation Testing

The following testing was performed on the MicroFuse Infuser to ensure conformance with the engineering design criteria and user functionality requirements. Specific testing procedures for certain performance attributes are detailed in the section on Product Validation.

Maximum Occlusion Pressure – To verify that the infuser's maximum occlusion pressure is below 45 psig for syringes (sizes 5 to 140 cc) and administration set tubing.

Rate of Travel Accuracy – To verify that the infusion delivery rates for both speeds meet the specification within ± 3%.

Drop Test – To determine if the infuser can withstand reasonable wear and tear in the field use environment. Must pass the drop test without major malfunction. Testing includes dropping packaged infusers from a height of 36 inches, and dropping infusers without a shipping container from a one-meter height onto a two-inch thick piece of red oak (ASTM-D5276).

Battery Installation – To ensure that the infuser is not affected by improper battery installation. Incorrect installation should result in no power input to the unit's electronics; no alarms should be activated. No changes or damage to the infuser should occur.

Gravity-Induced Flow – To verify that the infuser does not exhibit gravity-induced flow when hung from an IV pole by the wire bail or clamp mount. Testing is performed on all syringe sizes.

Battery Life Expectancy – To ensure that the infuser exhibits a life expectancy of at least 400 hours, operating at the Normal infusion rate, using two C-cell alkaline batteries.

Syringe Size Sensing – To verify that the syringe size sensor accurately detects the correct class size: small (5 – 12 mL), medium (20 – 60 mL) or large (100/140 mL) of the syringe installed on the infuser.

Alarm Functions – To verify that all alarms function according to the design specification. This includes the following visual and audible alarms: end-of-infusion/occlusion, low battery, internal malfunction, and return for required maintenance.

EMC/EMI Testing – To ensure that the infuser is not adversely affected by the presence of electromagnetic interference, and that it will not generate EMI beyond allowable limits. Testing performed by a qualified independent testing service.

Pressure Effects – To verify that the infuser is not affected by positive or negative pressure, and is capable of infusion against 100 mm Hg (1.93 psig).

Reliability – To ensure that the infuser operates reliably over its planned service life of approximately 5,000 infusion cycles. Testing includes the on/off switch, syringe clamp, and motor and gearbox components.

Syringe Acceptance and Retention – To verify that the infuser holds all specified syringes securely in place.

Size and Weight – To determine if the infuser meets size and weight requirements, and can be hung securely from an IV pole.

User Validation – To verify the utility of the infuser's ergonomic, electronic, and mechanical functions and ensure that the user's manual is clear, concise, and acceptable.

Operator Manual Verification and Validation – To ensure that the infuser's description, operating procedures, and supporting information is complete and adequate for device operation in the user's environment.

Key Engineering and Design Features

The MicroFuse Infuser incorporates a number of engineering improvements over our original syringe infuser design, including:

- **Sealed, surface-mounted, light-emitting diodes** (LED) for visual indicators.
- **Glass-filled ABS housing**, developed through mold flow analysis, to minimize molded-in stress and stress concentration points to provide a housing that is break resistant, visually appealing and comfortable to handle.
- **Sealed audio transducer** prevents fluid contact to allow the unit to be cleaned without risk of damage.
- **Dome switches** that provide tactile engagement feedback to the user.
- **Software-controlled operation** that eliminates the effects of hardware variation on product performance parameters.
- **High resolution pulsed flow** maintains a high level of accuracy and minimizes the stiction effects of continuous operation.
- **Automatic syringe size sensing** divides the wide range of syringe cross-sections into manageable ranges to ensure that adequate force is applied without exceeding the maximum pressure specification.
- **Larger screws** minimize the number of fasteners required and provide a significant safety factor of jack-out torque for the ultrasonically installed threaded inserts.
- The **center housing beam** eliminates the effects of shrinkage on the top and bottom housings to ensure proper alignment and engagement of the drive mechanism.
- **Recessed clamp and syringe driver arms** are close to the housing to protect these more fragile parts from the impact of dropping.
- **Wide contact area** for the IV pole clamp minimizes the torque required to securely attach the unit to an IV pole and prevents loosening due to movement during use. Attachment knob is large and ergonomically comfortable.

Product Validation

This section details the specific test protocols and results for the MicroFuse Infuser.

Product Specifications

Size (Length x Width x Height):	9.6 in x 2.7 in x 4.0 in 24.4 cm x 6.9 cm x 10.1 cm
Weight:	26 ounces (0.7 kg), with batteries
Materials of Construction:	Injection-molded plastic (housing, battery cover, syringe driver arm, syringe holder)
Compatible Syringes:	BD®, Monoject ®, Terumo®, other disposable syringes
Syringe Sizes:	5 to 140 cc
Accuracy of Flow Rate:	± 3% over 1.18 in (3.0 cm)
Flow Rates	
Standard Infuser:	NORMAL: – 5.5 in, 14 cm/hour SLOW: – 1.83 in, 4.7 cm/hour
Rapid Rate Infuser:	RATE 1: – 0.53 in, 1.35 cm/minute RATE 2: – 0.38 in, 0.97 cm/minute
Extended Rate Infuser:	RATE 1: – 5.5 in, 14 cm/hour RATE 2: – 0.133 in, 0.338 cm/hour
Typical Delivery Times	
Standard Infuser:	NORMAL: – 20 - 40 minutes SLOW: – 60 - 120 minutes
Rapid Rate Infuser:	RATE 1: – 4 - 6 minutes RATE 2: – 8 minutes
Extended Rate Infuser:	RATE 1: – 20 - 40 minutes RATE 2: – 8 – 24 hours
Power Requirement:	3.0 V dc (battery only)
Battery Life:	400 hours of operation, minimum 10 hours typical at low battery indication
Batteries:	Two (2) C-cell, alkaline only
Occlusion Detection Time:	< 3 minutes at NORMAL rate; standard infuser
Occlusion Pressure:	< 45 psig (2327 mm Hg); varies by syringe size and manufacturer
Back Pressure Effect:	None within ± 100 mm Hg
Mounting Options:	Built-in wire hanger or optional IV pole clamp
Alarms:	Occlusion, end-of-infusion, low battery, return for required maintenance, internal malfunction

Maximum Occlusion Pressure Testing

Pressure Sensing Design Description

The MicroFuse Infuser delivers fluid by periodically energizing a motor to move the syringe plunger a small distance. The motor is mechanically connected to the unit's syringe driver arm through a gear reduction system and a rack-and-pinion final drive.

Pressure sensing is part of the product's safety features. The infuser must not produce more than 45 psi pressure with any size syringe, to ensure that the syringe and administration set are not over-stressed. *NOTE: Most syringes and administration sets can withstand 90 psi or more, so a significant safety factor is inherent in the 45 psi specification.* Similarly, the syringe must be able to produce pressures of at least 2 psi so that fluid delivery can occur in the presence of normal infusion pathway pressures.

The infuser's pressure sensing system consists of current sensing electronics, syringe size sensing switches, an encoder on the gear train, and proprietary software algorithms. The current sensing electronics monitors the current drawn by the drive motor and provides that information to one of the processors. The syringe size switches consist of small dome switches that are contacted by the syringe barrel. Closure of one or both switches is used to classify the syringe size. The encoder on the gear train provides an independent verification that the drive motor is turning. The software combines data from the other three elements of the system to determine if an occlusion or end-of-infusion condition exists.

In operation, the MicroFuse Infuser periodically energizes the drive motor. As the motor is driven, motor current and encoder pulses are monitored. Changes in the rate of encoder pulses usually indicate that load on the syringe plunger has increased. This can occur because (a) friction has increased between the plunger and barrel; (b) infusion has ended because the plunger has "bottomed out" in the barrel; or (c) the administration set is occluded. The infuser responds to these cases by applying more current to the motor the next time it is energized. This response will overcome frictional variations and keep the delivery rate accurate. However, if the plunger has hit bottom, or if there is an occlusion in the delivery line, increasing the motor current will not allow the syringe driver arm to move much further. Eventually, motor current reaches a limit; if the encoder still does not indicate motor motion, an Occlusion/End-of-Infusion condition is identified.

The algorithms for concluding that an Occlusion/End-of-Infusion condition exists are complex and proprietary. They are based on motor current, encoder motion, and time. Further, alarm thresholds are modified by syringe size. This allows the MicroFuse Infuser to accommodate syringes from 5 to 140 cc safely. The infuser can deliver at least 2 psi in all cases, without exceeding 45 psi.

Tables in the MicroFuse Infuser Operator's Manual show the maximum and typical pressures that can be expected with a variety of syringe brands and sizes.

Test Background

Measurement of maximum occlusion pressure must be done carefully to achieve results comparable to those that are experienced by a user. Baxa Corporation has performed numerous tests to determine maximum pressures under a variety of operating conditions. That experience has led to the following test guidelines.

It should be noted that occlusion pressures show a significant variation from one test to the next. These variations are primarily due to (a) frictional variations in the syringe and

(b) mechanical position of parts in the MicroFuse when it is turned ON. In any series of tests for a given syringe, the highest occlusion pressure can be more than twice as large as the lowest occlusion pressure.

Test Materials

Use the following materials to measure maximum occlusion pressure:

(a) New (unused) syringe, 5 – 140 cc
(b) Water
(c) Pressure gauge
(d) Administration set matched to syringe size

Test Procedure

1. Fill the syringe with water. Syringe should be more than half filled.
2. Connect the administration set to the syringe.
3. Purge all air from the syringe and administration set.
4. Connect the free end of the administration set to the pressure gauge.
5. Install the syringe on the MicroFuse Infuser. The syringe barrel holder secures the syringe in place. The syringe barrel flange must be in the syringe flange slot on the infuser, and the end of the plunger must be in the slot in the syringe driver arm.
6. Turn the infuser ON. It can be running at either infusion rate. The alarm should not be muted.
7. Allow the MicroFuse Infuser to run until an Occlusion/End-of-Infusion alarm appears. Note the pressure on the gauge when the alarm occurs. (Depending on the starting conditions, syringe type, and amount of air within the pressure gauge, it may take 2 - 4 minutes for the alarm to occur.)

Rate-of-Travel Accuracy Testing

Mechanical Design

The MicroFuse Infuser delivers fluid through an administration line by depressing the plunger of a disposable syringe incrementally. The syringe is held in place by a spring-loaded syringe barrel holder. The syringe barrel flange is secured in a slot on the top of the infuser. The end of the syringe plunger is placed in a slot in the syringe driver arm.

The infuser drive system consists of a battery-powered motor, a gear reduction assembly, and a rack-and-pinion final drive. The rack is an integral part of the syringe driver arm that pushes on the syringe plunger. The syringe driver arm moves in a rectangular channel in the top of the infuser.

When the infuser is OFF, the pinion is not engaged with the rack. This allows the syringe driver arm to be manually adjusted for different syringe sizes and fluid volumes. When the infuser is turned ON, the pinion moves into engagement with the rack. Pinion rotation causes the rack to move, forcing the driver arm against the syringe plunger.

The drive motor is energized periodically, under processor control, to move the rack. At the NORMAL infusion rate (standard infuser), the motor will typically run for about 1 second, followed by a dwell period of about 9 seconds. This sequence repeats as long as

the infuser is ON and no alarm conditions are present. At the SLOW infusion rate (standard infuser), the motor runs for about 1 second, but the dwell period is increased to about 27 seconds. Load sensing circuitry in the MicroFuse Infuser maintains the desired infusion rate in the presence of loads produced by friction and pressure in the syringe.

Motion of the syringe driver arm for the standard infuser is 5.5 inches/hr for the NORMAL infusion rate. The driver arm moves at 1.83 inches/hr for the SLOW rate. The accuracy tolerance on these rates is ± 3%. These rates may be translated into volumetric delivery (i.e., cc/hour or cc/min) where the syringe size and manufacturer are known. Use the Infusion Time Charts in the MicroFuse Operator's Manual to determine flow rates.

Power for the MicroFuse Infuser is provided by two C-Cell batteries. The batteries are housed in a "caddy" on the end of the infuser. To release the caddy, unlock then depress the wings on either side of the caddy.

Test Background

Measurement of the rate of travel must be done carefully to achieve results that are not influenced by extraneous factors. Such factors include (a) mechanical "play" in the rack-and-pinion gear system; (b) positions of the rack and pinion when the infuser is turned ON; (c) the point during the motor run/dwell sequence when the infuser is turned OFF; and d) presence or absence of a typical load on the syringe driver arm.

Baxa Corporation has performed numerous tests to determine rate of travel accuracy. The following test guidelines were refined during the product development process. This protocol was successful in eliminating factors that tended to obscure the true rate of travel.

Test Materials

Use the following materials to measure rate of travel:
(a) Stopwatch
(b) New (unused) syringe, any size from 10 – 60 cc, air filled, uncapped
(c) Calipers with a 6-inch (or greater) measuring range

Test Procedure, Unloaded

1. Place the syringe on the MicroFuse Infuser. Be sure to put the barrel flange in the slot on the top of the infuser, and place the end of the plunger in the slot on the syringe driver arm. The spring-loaded syringe barrel holder will secure the syringe in place.
2. Turn the infuser ON. Allow it to run for about 1 minute. This will ensure any mechanical "play" is taken up by the drive system, and the plunger will start to move the syringe barrel.
3. Do <u>not</u> turn the MicroFuse OFF with the ON/OFF switch. Instead, unlock the battery caddy and squeeze its side "wings," then pull the caddy a few millimeters out from the infuser body. This will turn the unit OFF without disengaging the mechanical drive system.
4. Measure the distance between the syringe driver arm and the inside of the channel that guides it, using the caliper. This is the starting distance.
5. Simultaneously re-engage the battery caddy and start the stopwatch. This will put the MicroFuse Infuser delivery system in motion.
6. Allow the syringe driver arm to move at least 1.5 inches.

7. Simultaneously disengage the battery caddy and stop the stopwatch. This will halt motion of the drive system. This step should be done when the motor is not running.
8. Measure the distance between the syringe driver arm and the guide channel. This is the ending distance.
9. Subtract the ending distance from the starting distance to get the *total distance traveled*. Calculate the *rate of travel* by dividing the distance traveled by the elapsed time.

Test Procedure, Loaded

The infuser may be tested under realistic pressure loads by substituting a water-filled syringe for the air-filled syringe in Step 1 of the procedure above. An administration line of the appropriate inside diameter (ID) should be connected to the syringe.

1. Purge both the syringe and the administration line of air bubbles.
2. Place the end of the administration line at a height equivalent to ± 100 mm Hg pressure, relative to the syringe. *NOTE: When using water as the fluid, this height is 54 inches*. To simulate a pressure load –100 mm Hg, the end of the line must be below the syringe.
3. Place a container under the end of the administration line to catch fluid that is delivered.
4. Complete Steps 2 – 9 in the above procedure.

Technical Issues

This section addresses some of the common questions related to maintenance and usage of the MicroFuse Infuser. If you have additional questions or concerns, please contact Baxa Customer Support at 800-567-BAXA (2292).

MicroFuse Troubleshooting Guide	
Symptom	**Solution**
Infuser will not change flow rates.	• Press and hold rate button for two full seconds. • Check Rate Lockout switch in battery caddy compartment.
Occlusion alarm is indicated in error. Infusion times do not match the reference charts.	• Administration set must match the specifications indicated in the Operator Manual. • Incompatible sets may cause false occlusion alarms or affect infusion times.
Cannot move the syringe driver arm to load syringe plunger.	• Check that the ON/OFF switch is fully in the OFF position.
Infuser alarm indicates internal malfunction.	• Turn infuser OFF, then ON to reset. • If alarm reappears, return unit for service.
Slow flashing alarm before IV infusion is complete.	• Check the IV set or catheter for occlusion. • Clear occlusion and restart infuser.
Infuser is ON, but will not flow.	• Check that administration set slide clamp has been released. • Verify that the syringe driver arm is engaged with syringe plunger.
Batteries have been replaced, but unit will not turn on.	• Remove battery caddy and check the battery orientation to ensure proper placement. • Check that the battery caddy is seated snugly in the infuser body.
After battery change, or battery caddy removal, infuser alarm indicates internal malfunction or low battery light appears.	• Turn infuser OFF, then ON to reset microprocessor.
Repeating chime is sounded and the infuser will not function.	• Replace batteries with a fresh set. • Always replace both batteries at the same time to ensure proper battery life.
Repeating chime is sounded, alarm lights flashing, and unit will not function. Alarm lights remain lit when unit is OFF.	• Return unit for required maintenance.

The Complete System for Syringe Infusion

Baxa is the only supplier that offers a complete system of technical reference, support materials and products to make syringe infusion easy to implement and cost effective:

- Complete pharmacy technical reference materials: written guidelines, procedures and documentation, dilution tables and stability reference materials
- Nursing reference manual for floor implementation and in-servicing
- Training video for "quick instruction" or in-servicing
- Easy-to-follow Operator Manual
- Quick Instructions cards for point-of-use reminders
- Cost-benefit and system analyses
- Technical and professional assistance
- A complete line of syringe infusion accessories, including:
  - Waist pack for personal ambulatory use
  - Label-Ease™ Syringe Labeling System and Software
  - Pole mount clamp for infuser
  - Repeater™ Pump for accurate syringe filling
  - IV admixture products for venting, filling and transfer applications

Contact Baxa Corporation for a catalog or samples.

MicroFuse Administration Sets

The MicroFuse Infuser features the most complete syringe size sensing in its class of devices. However, certain clinical situations requires consideration of the set tubing internal diameter (ID). Baxa offers a variety of administration sets specifically designed for use with the MicroFuse Infuser. These sets minimize patient fluid volumes and will not kink or occlude. The larger diameter sets are offered for infusion of more viscous fluids and use with the largest syringe sizes.

Standard Microbore Administration Set
0.020 inch ID, Order Nos. H938 **601** 5 and H938 **6015** 5 , 60-inch set with slide clamp
This diameter is the industry standard, and is effective for virtually all syringe infusion applications. Prime volume < 0.4 mL.

Minibore Administration Set
0.030 inch ID, Order No. H938 **602** 5, 60-inch set with slide clamp, prime volume < 0.8 mL
This set provides an alternative for syringes ≥ 60 mL and for viscous drugs, which can cause some syringe infusers to sound false occlusion alarms. The syringe size sensing feature in the MicroFuse Infuser should prevent such alarms.

Smallbore Administration Set
0.040 inch ID, Order No. H938 **6045** 5, 60-inch set with slide clamp, prime volume < 1.5 mL
This set provides an alternative for the large 100/140 mL and larger syringes and for viscous drugs, which can cause some syringe infusers to sound false occlusion alarms for high back pressure. The syringe size sensing feature in the MicroFuse Infuser should prevent such a false alarm if this larger diameter set is used.

Smallbore Administration Set for Rapid Rate Infusions
0.030 inch ID, Order No. H938 **607** 5 and H938 **6075** 5, 30-inch set with slide clamp; prime volume < 0.4 mL
This set is designed specifically for use with the MicroFuse Rapid Rate Infuser where substantial fluid volumes are infused over short time periods. The shorter, larger ID set is necessary to prevent excess back pressure.

Installing the Pole Mount Clamp

The MicroFuse Pole Mount attaches the infuser to a standard healthcare bedside pole. The Clamp fits poles from ½ to 1 ¼ inches in diameter. Complete instructions and drawings for pole mount installation on the MicroFuse Infuser are included in the product data sheet, part number 5300-0722.

To install the pole mount clamp:

1. Read through the instructions first, to familiarize yourself with the simple procedures. NOTE: these instructions are intended for a permanent pole mount installation.
2. Slide the infuser ON/OFF towards the ON position about ¼ inch (0.6 cm). This releases the syringe driver arm, allowing it to move freely.
3. Move the syringe driver arm up and down. The arm should move this freely after the pole mount has been installed.
4. Place a rubber band around the narrow end of the MicroFuse Infuser to hold the unit together during installation.
5. Remove the two bottom screws from the wide end of the infuser. Note where the screw was removed, so that it is returned to the correct hole.
6. Clean the screw threads of any dried Loctite® glue (blue flakes), using a dry brush or cloth.
7. Align the pole mount with the knob towards the front of the infuser.
8. Apply a thin line of Loctite-242 to the threads, then return the screws to their original holes.
9. Begin to thread the screws by hand, completing the process with a flathead screwdriver. NOTE: The Loctite glue holds the screws in place. *It is important not to over-tighten the screws.*
10. Move the syringe driver arm to see that it still moves freely. If the screws are too tight, the arm will bind. Back off the screws slightly to release resistance. NOTE: It is critical that the syringe driver arm move freely. Resistance may cause false occlusion alarms.

Cleaning and Disinfection

Exterior infuser services may be cleaned using a damp cloth and mild detergent. Use a mild germicide to disinfect. *The infuser cannot be immersed or flushed with any solution*. Do not sterilize using EtO gas or steam autoclave.

Service and Repair

The MicroFuse Infuser has been designed to withstand rigorous use in a hospital or homecare environment without maintenance. To reduce manufacturing costs, and improve durability, the product is designed as an integrated unit with no user-serviceable parts. The infuser was designed for safety and simplicity. Specific design inputs addressed the need for reliability and durability to prevent unit downtime. The MicroFuse Infuser requires no calibration and no internal adjustment as its operations are entirely software controlled. Eliminating the need for preventive maintenance ensures that the unit is working appropriately and maximizes its service time on the floor.

Opening the infuser body will compromise the unit's resistance to fluids and may result in a malfunction or electrical short. In order to ensure the proper operation of the MicroFuse Infuser, defective units should be returned to the manufacturer so that quality testing can be performed and the unit recertified.

The standard MicroFuse Infuser has been designed to operate for 2500 hours before it requires maintenance. On activation, the infuser checks all major functions and an alarm is indicated if a malfunction is detected. If an infuser malfunctions, or is defective for any reason, it should be returned to an authorized agent for repair or replacement.

Inspection

Medical equipment may be inadvertently dropped or damaged in transport. MicroFuse Infusers should be inspected periodically for visible cracks or damage to the infuser housing. Dropped infusers may incur internal damage. To check for unit damage:

- Inspect the battery housing for damage.
- Batteries should fit snugly in the battery caddy, and the caddy must seat firmly into the infuser body.
- Turn power ON to verify that the syringe driver arm is locked into position.
- Run a Flow Rate Test to verify delivery accuracy.

Flow Rate Test

The rate of travel of the syringe driver arm may be tested as follows:

1. Set the Flow Rate switch to NORMAL.
2. Set the syringe driver arm as far toward the hanger as possible (maximum travel).
3. Slide the Power ON/OFF switch to ON.
4. Measure the time until the End of Infusion alarm occurs. The time should be 44 to 47 minutes.

Battery Replacement

The MicroFuse Infuser operates with two C-cell alkaline batteries. Batteries are accessed by unlocking the battery caddy at the side of the unit and squeezing the caddy tabs. Pull out caddy. Load new batteries into the holders, according to the orientation indicated. Replace the battery caddy and lock. NOTE: Always replace both batteries at the same time with fresh batteries.

Rate Lock Out

For customers who prefer to limit the infuser to a single rate, a simple procedure will restrict the MicroFuse Infuser to one of the two pre-set infusion rates.

To "lock" the infuser on a single rate:

1. Set the desired infusion rate using the Flow Rate switch. Either NORMAL or SLOW (Rate 1 or 2 on specialized infusers) can be locked.
2. Release and remove battery caddy.
3. Slide the LOCK/UNLOCK switch inside the battery compartment to LOCK. This fixes the Flow Rate at the selected rate.
4. Replace the battery caddy.
5. Repeat the procedure and set the switch to UNLOCK to allow rate selection again.

Product Service Policy

See the MicroFuse Operator Manual for complete information on Product Warranty. If not covered by warranty, the MicroFuse Infuser may be repaired or replaced with all costs, including parts, labor, and shipping, invoiced to the customer. A minimum service fee is charged. If a non-warranty infuser is exchanged, the cost of repairing the returned infuser to a condition equivalent to the exchanged infuser will be the amount invoiced to the customer. Customers are given a repair cost estimate and approval must be received before repairs are made.

Trademarks

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